Complementary Therapies in Medicine (2014) 22, 220–225

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The effect of olive oil and the Saj® cream in prevention of striae gravidarum: A randomized controlled clinical trial☆

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Available online 31 January 2014

KEYWORDS
Striae of pregnancy;
Treatment;
Prevention;
Olive oil;
The Saj® cream

Summary
Objective: To compare the clinical efficacy of olive oil and the Saj® cream on the occurrence and severity of striae gravidarum.
Design: Parallel randomized controlled clinical trial.
Setting: West Health Centre, Lolagar and Akbarabadi Hospitals, Tehran, Iran.
Interventions: 360 Nulliparous women at their second trimester of pregnancy randomly (simple randomization) allocated into three groups of olive oil, the Saj® cream, and control that finally 150 of them (50 subjects in each group) completed the study. Control group did not receive any medication/intervention. At gestational age of 38–40 weeks the participants were evaluated regarding the occurrence of striae on abdominal skin and its severity that were primary outcome of the study.
Results: In the olive oil group, striae occurred in 72% of the participants, which were mild, moderate, and severe in 32%, 26%, and 6% of the cases, respectively. In those who received Saj® cream, striae occurred in 64% of the cases, which were mild, moderate and severe in 16%, 34%, and 14% of the cases, respectively. With regard to the control group, striae occurred in 60% of the participants, among which striae were mild, moderate, and severe in 22%, 24%, and 14% of the cases, respectively. There were no statistically significant differences among the three studied groups regarding the incidence or severity of striae.
Conclusion: Neither olive oil nor the Saj® cream were effective in preventing the occurrence of striae gravidarum or affecting its severity. Further studies to examine the effect of other herbal/chemical preparations on occurrence of striae gravidarum are recommended.
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☆ *Registration*: This trial was registered in IRCT registration with number IRCT138807282172N2.

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http://dx.doi.org/10.1016/j.ctim.2013.11.011

Introduction

Striae of pregnancy are one of the most common skin changes of pregnancy (seen in 50—90% of pregnancies). It represents as slightly retracted red[1] and purple[2] streaks on the skin of the abdomen, and sometimes the breasts, thighs, and axillae.[1] The lesions are usually accompanied by itching.[3] In more than 90% of the cases, the striae occur in the third trimester of pregnancy.[1,3,4] The length of the streak is usually a few centimeters, with the width of 1—10 mm.[3]

Although the major etiology of striae gravidarum is not specified,[4] some causative factors are genetic susceptibility,[5] family history, skin type and its color, young age at the time of pregnancy, child's birth weight,[3,4] malnutrition,[3] and gestational diabetes.[6] This dermatologic condition may result in cosmetic concerns for mother,[7] and in some cases it would cause problems in self-image,[8] loss of self-esteem, and psychological problems.[9]

Many women who are going to become pregnant for the first time may ask their health care providers about prevention of striae gravidarum.[3,10] Although, so far no definite method has been proposed for treatment of striae of pregnancy, different studies have proposed different ideas in this respect. Moreover, many women use different types of creams and lotions such as vitamin E cream and Trofolastin cream which contains tocopherol and collagen-elastin hydrolysates.[11]

In Iran, the Saj cream® is produced by a local company (Seoidrood Co., Iran). It contains lanolin, stearin, triethanolamine, almond oil, and bizovax glycerin amidine. These materials can maintain the balance of normal skin moisture, and facilitate the steps of skin regeneration. Therefore, the cream has been recommended by the manufacturer for prevention of loosening of abdomen and breast skin during the pregnancy.[12]

Oils such as cocoa butter, almond oil, glycerin,[10] and olive oil have been used during pregnancy for this purpose, but enough evidence to support their effectiveness is not available.[4] In fact, the lotions and creams reduce the skin dryness and can be used to manage itching sensation accompanying striae of pregnancy.[12] Olive oil is one of the oils of plant origin used for the treatment of striae, and is rich in vitamin E.[3] In the comparative study carried out by Poidevin and Sydney on 116 women, it was concluded that topical administration of olive oil is not effective in prevention of striae of pregnancy.[13] However, Davey carried out a retrospective study by asking 70 women in the post-partum period, and olive oil was considered as one of the items that reduced the striae.[14]

In pregnancy and post-partum period, one of the important roles of midwifery services is to improve the physical, psychological, and personal health level of pregnant women. It should be considered that according to our experience, many women experience stress in pregnancy and post-partum period about development of striae. Therefore, the current study was performed to compare the clinical efficacy of olive oil and the Saj® cream on the development and severity of striae gravidarum.

Materials and methods

This study was a parallel randomized controlled clinical trial that was conducted at the West Health Centre, Lolagar and

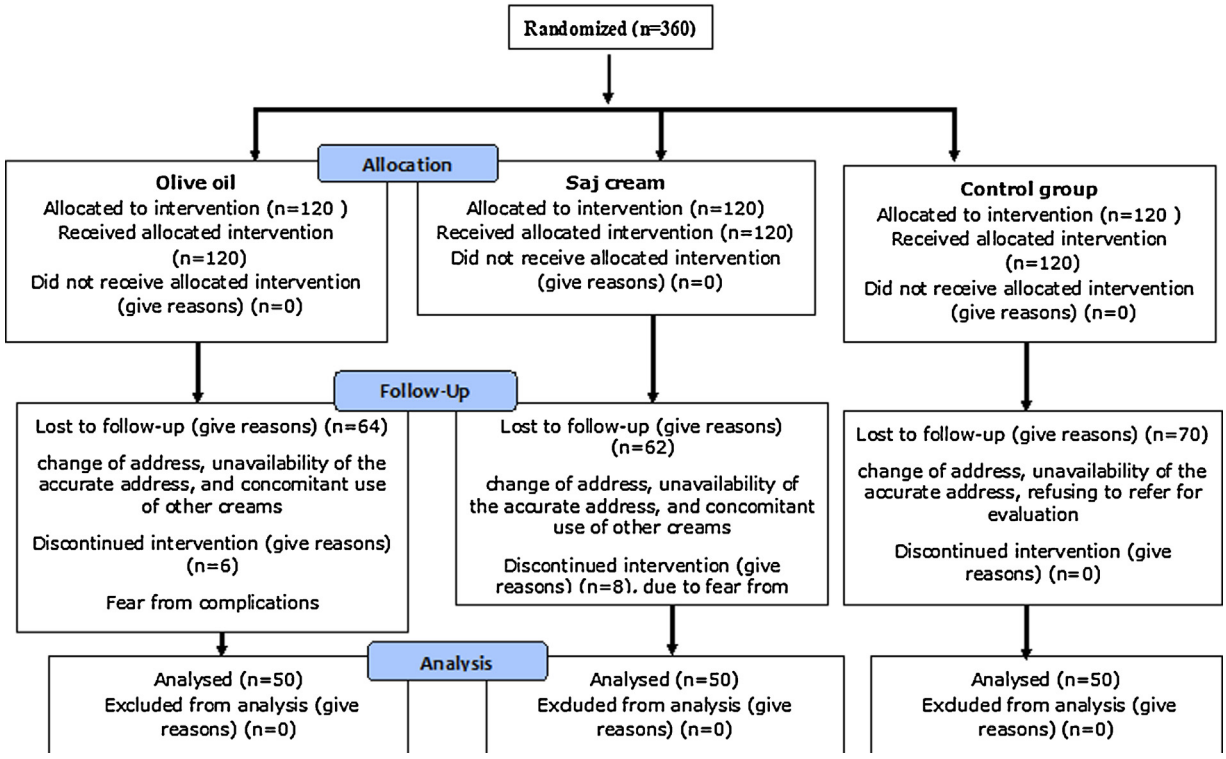

Figure 1 The study flow diagram.

Table 1 Demographical characteristics of the participants in the three groups of olive oil, Saj® cream, and control.

		Olive oil ($n=50$)	Saj® cream ($n=50$)	Control ($n=50$)
Age, mean (±SD)		23 (±2.7)	24.2 (±3.3)	23.8 (±2.6)
Number of miscarriages		4 (8%)	1 (2%)	2 (4%)
Education level	Below high school diploma	9 (18%)	18 (36%)	21 (42%)
	High school diploma	34 (68%)	26 (52%)	23 (46%)
	Academic	7 (14%)	6 (12%)	6 (12%)
Positive history of striae in family		36 (72%)	32 (64%)	30 (60%)
Skin color	Light	41 (82%)	48 (96%)	38 (72%)
	Dark	9 (18%)	2 (4%)	12 (24%)

Akbarabadi Hospitals, Tehran, Iran from August 2009 to May 2010.

The study population consisted of nulliparous females with gestational age of 18—20 weeks and the age ranged from 20 to 30 years. The range of body mass index (BMI) was from 18.5 to 25.

After the study objectives were described for the participants, written informed consent was obtained and they were informed that they could quit the study whenever they desire. The study protocol was approved by the ethics committee at Tehran University of Medical Sciences, Tehran, Iran.

The subjects were randomized by simple randomization into 3 groups: olive oil, the Saj® cream, and control. Although the study calculated sample size was 150 (50 in each group), but considering lost to follow-ups, 360 pregnant women were included in the study at the beginning. However, during eight months of sampling and follow-up, 210 cases were excluded for different reasons such as change of address, unavailability of the accurate address, fear from complications of the interventions, and concomitant use of the Saj® cream and olive oil or other creams. The final analysis was performed on 150 participants (three groups, each consisting of 50 women). The study flow diagram has been shown in Fig. 1. Occurrence of striae and its severity were primary outcomes of the study.

Exclusion criteria were twin pregnancies, polyhydramnios, and development of a skin disease, corticosteroid usage, and application of any other cream on the abdominal skin. The subjects were asked to apply the medication three days weekly.

The subjects of olive oil group were instructed to apply 1 cm^3 of olive oil twice daily on the skin of abdomen gently without massage. The Saj cream subjects were instructed to apply 1 cm of this cream (about two grams) twice daily on the skin of abdomen without massage. The control group used no cream or oil during pregnancy. The subjects were followed until gestational week of 38—40. The subjects were followed weekly by phone and their questions were replied by the research team staff.

The data gathered were age, educational level, gravid, miscarriages, and gestational age at the time of examining the striae, weight before intervention, weight after intervention, the history of striae in close family members, and the type of skin. Since olive oil and the Saj cream had different shapes and control group did not receive any intervention, study blinding was not applicable. To reduce any bias, the striae were examined at the end of the second trimester. The only study blinding was in outcome assessment. Occurrence and severity of striae as the study outcomes were assessed by a blinded assessor that was not aware of the study groups.

Presence and severity of striae was assessed by the Davey method.[14] To determine the severity of striae, the abdomen surface was divided into four quadrants using two straight lines which cross each other at the umbilicus. According to the severity of involvement, scores were assigned as follows: 0 (no striae in any quadrant), 1 (striae which do not affect a quadrant completely), 2 (striae which affect a quadrant completely). According to this scoring system, mild stria was defined as scores 1—3, moderate as 4—6, and severe as 7 or 8.

Table 2 Frequency distribution of striae in olive oil, Saj® cream, and control groups at the end of study.

	Group					
	Olive oil		Saj® cream		Control	
	n	%	*n*	%	*n*	%
Positive for striae	32	64	32	64	30	60
Negative for striae	18	36	18	36	20	40
Total	50	100	50	100	50	100
Result of the chi-squared test	$\chi^2 = 1.648$, df = 2, $p = 0.439$					

Table 3 Frequency distribution of severity of striae in olive oil, Saj® cream and control groups at the end of study.

Severity of striae	Group					
	Olive oil		Saj® cream		Control	
	n	%	*n*	%	*n*	%
Absent	18	36	18	36	20	40
Mild	16	32	8	16	11	22
Moderate	13	26	17	34	12	24
Severe	3	6	7	14	7	14
Total	50	100	50	100	50	100
Result of chi square test	$\chi^2 = 5.825$, df = 6, $p = 0.443$					

Statistical analyses

To report data, descriptive indices such as frequency, percentage, mean, and standard deviation were used. To compare the frequency of striae and other categorical variables among the study groups, chi-square test was used. To compare numerical variables, ANOVA test was applied. All statistical analyses were done using the SPSS software for Windows (Ver. 16.00).

Results

Mean (±SD) ages of olive oil, the Saj cream, and control groups were 23.8 (±2.7), 24.2 (±3.3), and 23.8 (±2.6) years, respectively. The highest academic degree was high school diploma in all groups. Most women participated in the study (93%) did not have the history of miscarriage. The three groups were not different in terms of having the history of miscarriage. Moreover, in 58% of the participants, the history of striae of pregnancy in their first-degree relatives was positive, and according to the results of chi-square test, the three groups were not significantly different in this respect. Most women studied had light skin color, and the three groups were not significantly different in this respect. Table 1 presents general characteristics of the three studied groups.

Table 2 presents the frequency of subjects with striae in each group. As shown, the three groups were not significantly different with respect to the frequency of striae ($P = 0.43$).

Table 3 presents the severity of stria in olive oil, the Saj cream and control groups. As shown, there was no significant difference between the 3 groups.

Discussion

According to the results provided above, olive oil and Saj cream® had no significant effects on development and severity of striae gravidarum. In a study in Japan, Belda et al. reported the prevalence of striae gravidarum as 56%.[11] Our results are consistent with their findings.

Table 3 provides the data about severity of striae. It was observed that in the control group, the percentage values of mild, moderate, and severe striae were 22%, 24%, and 14%, respectively. In the study carried out by Ottoman et al., the frequency rates of mild, moderate, and severe striae were 17%, 18%, and 18%, respectively.[8] Our results were almost similar to their findings. This is while the results obtained in the study performed by Atwal et al. was different from our findings, and mild, moderate, and severe striae were observed in 62%, 26%, and 12% of the participants, respectively.[15]

According to Table 2, in the olive oil group, striae gravidarum occurred in 64% of the participants. Poidevin and Sydney reported the frequency of striae gravidarum as 60% in those who received olive oil.[13] the results obtained in the current study are consistent with the findings of Poidevin and Sydney. In the study carried out by Davey,[14] the prevalence of striae in those who used topical olive oil found to be 26%. The difference between our findings and those reported by Davey may result from the type of study. Since cocoa butter is plant oil, the study carried out by Osman et al.[8] can be compared with the current study. Osman et al. performed a study on the prevalence of striae gravidarum in pregnant women received cocoa butter, and reported the prevalence rate as 45%.[8] Our results are not in agreement with those reported by Osman et al., which may be due to the difference in sample size.

The data presented in Table 3 indicate that following the use of olive oil, the frequency rates of mild, moderate, and severe striae were 32%, 26%, and 6%, respectively. In the study carried out by Davey,[14] it was reported that the prevalence rates of mild and moderate striae gravidarum in women who used olive oil together with massage therapy were 22% and 2.9%, respectively, and severe striae was not observed.[14] In this respect, the results obtained in the current study are different from those reported by Davey. Davey study[14] was a retrospective study without control group but our study was a prospective trial with control group. Osman et al. reported the rate of mild, moderate, and severe striae as 20.5%, 21.8%, and 9%, respectively. The frequencies of moderate and severe striae observed in the current study are consistent with the findings of Osman et al., but the findings of the two studies were different with respect to the frequency of mild striae.

Tables 2 and 3 provide the data on determination of severity of striae gravidarum in the Saj® cream group. Table 2 shows that 64% of the participants in the Saj cream group experienced striae. It should be noted that application of Saj® cream for prevention of striae gravidarum was carried out for the first time as a clinical trial in Iran. The ingredients of Saj® cream are lanolin, stearin, triethanolamine, almond oil, and bizovax glycerin amidine.[12] In the study carried out by Behina and Hoseini, the occurrence of striae in pregnant women who received almond oil and glycerin were 66% and 71%, respectively.[10] Our results are relatively in agreement with those reported by Behina and Hoseini.

Belda et al. carried out a clinical trial in Japan to determine the effect of topical application of Trofolastin in prevention of striae gravidarum. They reported the frequency of striae gravidarum as 36%, which is different from our findings. The difference could be attributed to the difference in sample size.[11]

Table 3 on the severity of striae indicates that the frequency rates of mild, moderate, and severe striae after application of Saj cream were 16%, 34%, and 14%, respectively. In the study carried out by Behina and Hoesini in Tehran, among the women who received almond oil, the frequency of mild, moderate, and severe striae gravidarum were reported to be 30%, 32%, and 7.5%, respectively.[10] The results of our study are in agreement with the findings of Behnia and Hosseini with regard to the moderate severity of striae; however, the two studies are different in mild and severe striae. Behina and Hooseini reported the prevalence rates of mild, moderate, and severe striae in those who received glycerin 30%, 34%, and 9.4%, respectively.[10] Our results were consistent with their reports with regard to moderate and severe striae, but the two studies were different with respect to the prevalence of mild striae.

In another study, Poidevin and Sydney carried out a prospective study on 116 nulliparous women with the gestational age of 14 weeks or below to the end of pregnancy to determine the relationship between adrenal cortex hyperactivity and striae gravidarum. They evaluated the effect of topical application of olive oil and massage therapy on abdominal skin. Striae of pregnancy were observed in 68% of the 50 women who took olive oil and also in 55% of the 66 participants of the control group. Thus, they stated that application of olive oil is not effective in prevention of striae gravidarum development.[13] In our previous study we observed a similar effect in application of olive oil with its usage to the end of the second trimester.[16]

The main strengths of our study were its prospective design, random allocation and having control group.

As olive oil and the Saj cream had different forms and control group did not receive any intervention, study blinding was not applicable. Also, we could not prepare appropriate placebo for control group. These are main limitations and weaknesses of the present study. The other limitation is that we started application of olive oil and the Saj cream from second trimester of pregnancy (gestational age: 18—20 weeks).

Since striae gravidarum has been associated with psychological problems and reduction in self-esteem in women and there is no curative therapy for that, it is necessary to find a preventive method to prevent its development.

Future randomized placebo controlled clinical trials with greater sample size and application of olive oil and the Saj cream from beginning of pregnancy (first trimester) is recommended to investigate their efficacy on prevention of striae gravidarum development. Also, we recommend investigation of the effects of other herbal oils such as sesame oil, almond oil, coffee beans oil on prevention of striae gravidarum development.

Conclusion

Neither olive oil nor the Saj® cream was effective in reducing the incidence and/or severity of striae gravidarum in nulliparous women. Carrying out further research on other plant oils such as almond oil, glycerin, and cocoa butter; and also creams available on market, particularly those produced by local companies, is suggested. The studies could be performed to achieve the most desirable preventive effect in development of striae and control of its severity; and thus, regarding the safety of the oils and creams, if desirable effectiveness are achieved, they can be used in pregnancy in future studies.

Conflict of interest statement

None declared.

Funding

This study is supported by Deputy of Research of Medical Science University of Iran and the Sepidroo Company, manufacturer of beauty and health products.

Acknowledgements

The authors wish to thank the Research Chancellor of Tehran University of Medical Sciences for their financial support. Moreover, the cooperation of managers and staff of West Health Center, and Loulagar and Shahid Akbarabadi Hospitals in fulfillment of the research is highly appreciated. We wish to thank Farzan Institute for Research and Technology for technical assistance.

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